

Notice of Allowability

Application No.

10/042,091

Examiner

William W. Moore

Applicant(s)

DARROW ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to the amendment filed 20 January, and the interview conducted 02 April 2004.

☒ The allowed claim(s) is/are 15, 16 and 28-33.

☐ The drawings filed on _____ are accepted by the Examiner.

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 20 January 2004

☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material


5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 02 April 2004.

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER

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EXAMINER'S AMENDMENT

Applicant's Amendments filed January 20, 2004, to the first page of the specification and to claim 15, and adding the new claims 28 and 29, were entered. Claims 1-14 and 16-27 were canceled at Applicant's request. The amendments filed January 20, 2004, overcome rejections of record of claims herein both under 35 U.S.C. § 112, first and second paragraphs, and over the prior art. Claims 15 and 16 are amended below, claims 30, 31, 32, and 33 are added, and claims 15, 16, and 28-33 are allowed herewith.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Rewrite claims 15 and 16 thus:

15. (Amended) A method of identifying compounds that inhibit ~~modulate~~ protease EOS activity, comprising:

(a) combining a candidate inhibitor ~~modulator~~ of protease EOS activity, a protease EOS having an amino acid sequence as set forth in SEQ.ID NO.7 or SEQ.ID NO.9, and a labeled chromogenic substrate; and,

(b) measuring the rate of a change in the labeled chromogenic substrate in the presence and absence of the candidate inhibitor,

whereby an inhibitory compound is identified by a decreased rate of change in the labeled substrate relative to the rate of change in the labeled substrate observed in the absence of a candidate inhibitor.

16. (Amended) The method of claim 15 wherein the labeled chromogenic substrate is selected from the group consisting of fluorogenic, and colorimetric, ~~radiometric, and fluorescent resonance energy transfer (FRET)~~ substrates.

Add the new claims 30-33:

30. (New) The method of claim 16 wherein the fluorogenic substrate is a fluorescent resonance energy transfer (FRET) substrate.

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31. (New) A method of identifying compounds that inhibit protease EOS activity, comprising:

(a) combining a candidate inhibitor of protease EOS activity, a protease EOS having an amino acid sequence as set forth in SEQ.ID NO.7 or SEQ.ID NO.9, and a labeled radiometric substrate;

(b) separating a radiometric label from a cleaved substrate; and,

(c) measuring the rate of a change in the separated labeled radiometric substrate in the presence and absence of the candidate inhibitor,

whereby an inhibitory compound is identified by a decreased rate of change in the labeled substrate relative to the rate of change in the labeled substrate observed in the absence of a candidate inhibitor.

32. (New) The method of claim 31 wherein the protease EOS has the amino acid sequence set forth in SEQ.ID NO:7.

33. (New) The method of claim 31 wherein the protease EOS has the amino acid sequence set forth in SEQ.ID NO:9.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Linda S. Evans on April 2, 2004.

The following is an examiner's statement of reasons for allowance:

The examiner's amendment to claim 15 removes subject matters that are methods to identify modulators which activate serine protease activity – because activators of unmodified, or native, serine proteases are not known in the prior art or discussed in the specification – and partitions claimed methods to separate assays that use chromogenic substrates – where removing cleaved substrates from a combination of clause (a) is unnecessary to measure differences in rate between inhibitor-comprising assays and a control assay - from assays that use radiometric substrates where measuring the results requires a separation step. The examiner's amendment thus adds new claims 31-33 to

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describe radiometric assays originally included in claim 15 and the new claims 28 and 29. The amended claim 15 and new claim further state terminal clauses that complete the identification required in the claims' preambles. Claim 16 is amended above to state a proper Markush group by separating a subclass of compounds from one class, fluorogenic substrates, of the two classes remaining in the amended claim 16 and the new claim 30 added by examiner's amendment, depending from claim 16, returns that subclass of substrates to the subject matters claimed herein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
April 2, 2004


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER